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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/646,390	08/21/2003	Mitinori Saitou	674558-2002.1	1543

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EXAMINER	
GAMETT, DANIEL C	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 05/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/646,390	SAITOU ET AL.	
	Examiner	Art Unit	
	Daniel C. Gamett	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 25 August 2003.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-54 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-54 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 2-7, 24, and 27 in total, and claims 1, 23, and 26 in part, drawn to the GCR1 (Fragilis) polypeptide, classified in class 530, subclass 350.

II. Claims 11-13, 18, and 21 in total, and claims 8-10, 17, and 20 in part, drawn to the GCR1 (Fragilis) nucleic acid, classified in class 536, subclass 23.5.

III. Claims 35 in part, and 36, drawn to antibodies specific for GCR1 (Fragilis) polypeptide, classified in class 530, subclass 387.1.

IV. Claims 29-34, 37, and 41-43, each in part, drawn to methods of identifying pluripotent cells comprising detecting presence of a GCR1 (Fragilis) polypeptide, classified in class 435, subclass 7.21.

V. Claims 46-49 and 51-53, each in part, drawn to transgenic non-human animals comprising GCR1 (Fragilis) nucleic acid, classified in class 800, subclass 8.

VI. Claim 50 in part, drawn to a method of identifying a compound which is capable of interacting specifically with a GCR1 (Fragilis) protein comprising use of a transgenic non-human animal comprising GCR1 (Fragilis) nucleic acid, classified in class 800, subclass 3.

VII. Claim 54 in part, drawn to a nucleic acid construct for functionally disrupting a GCR1 (Fragilis) gene in a host cell, classified in class 536, subclass 24.5.

VIII. Claims 38 and 39, drawn to a pluripotent cell identified by detecting presence of a GCR1 (Fragilis) polypeptide or a GCR2 (Stella) polypeptide, classified in class 435, subclass 325.

IX. Claims 25 and 28 in total, and claims 1, 23, and 26 in part, drawn to the GCR2 (Stella) polypeptide, classified in class 530, subclass 350.

X. Claims 14-16, 19, and 22 in total, and claims 8-10, 17, and 20 in part, drawn to the GCR2 (Stella) nucleic acid, classified in class 536, subclass 23.5.

XI. Claim 35 in part, drawn to antibodies specific for GCR2 (Stella) polypeptide, classified in class 530, subclass 387.1.

XII. Claims 29-34, 37, and 41-43, each in part, drawn to methods of identifying pluripotent cells comprising detecting presence of a GCR2 (Stella) polypeptide, classified in class 435, subclass 7.21.

XIII. Claims 46-49 and 51-53, each in part, drawn to transgenic non-human animals comprising GCR2 (Stella) nucleic acid, classified in class 800, subclass 8.

XIV. Claim 50 in part, drawn to a method of identifying a compound which is capable of interacting specifically with a GCR2 (Stella) protein comprising use of a transgenic non-human animal comprising GCR2 (Stella) nucleic acid, classified in class 800, subclass 3.

XV. Claim 54 in part, drawn to a nucleic acid construct for functionally disrupting a GCR2 (Stella) gene in a host cell, classified in class 536, subclass 24.5.

XVI. Claims 40, 44,and 45, drawn to a method of isolating a gene specifically expressed in a pluripotent cell, classified in class 435, subclass 91.1.

Note: The Examiner has interpreted claim 32 as being drawn to a method according to claim 29 on the assumption that the current recitation of claim 15 was not the Applicant's intent.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I-VII are unrelated to inventions IX-XV. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different groups of inventions each recite or utilize distinct polypeptides, designated GCR1 (Fragilis) or GCR2 (Stella), respectively. These two polypeptides are not disclosed as being related to one another structurally or functionally, their only relationship being that they are expressed in the same cell. Thus these polypeptides (Inventions I and IX), their respective encoding nucleic acids (Inventions II and X), antibodies (Inventions III and XI), transgenic animals (Inventions V and XIII), constructs (Inventions VII and XII), and all claimed methods of using (Inventions IV, VI, and XII, XIV) are patentably distinct. Furthermore, as they are unrelated to one another, each product or method would require a separate, non-coextensive consideration of prior art, and thus simultaneous consideration of both GCR1 (Fragilis) and GCR2 (Stella) would create a serious search burden.

3. Inventions I-XV and XVI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the

invention of Group XVI is a method of gene discovery that does not rely upon, utilize, or recite any of the products or methods of groups I-XV.

4. Inventions I, II, III, V, VII, and VIII are independent and distinct, each from each other, because they are products that possess characteristic differences in structure and function and each has an independent utility that is distinct for each invention which cannot be exchanged.

a. In the instant case although the nucleic acids of Invention II encode the polypeptides of Invention I, Inventions I and II are distinct because they are physically and functionally distinct chemical entities, and the protein product can be made by another and materially different process, such as by synthetic peptide synthesis or by purification from the natural source. Further, the nucleic acid can be used for processes other than the production of the polypeptide, such as in hybridization assays. Furthermore, searching the inventions of Groups I and II together would impose a serious search burden. In the instant case, the search of the polypeptides and the polynucleotides is not coextensive. The inventions of Groups I and II have a separate status in the art as shown by their different classifications. In cases such as this one where descriptive sequence information is provided, the sequences are searched in appropriate databases. There is also search burden in the non-patent literature. Prior to the concomitant isolation and expression of the sequence of interest there may be journal articles devoted solely to polypeptides which would not have described the polynucleotide. Similarly, there may have been "classical" genetics papers which had no knowledge of the polypeptide, but spoke to the gene. Searching, therefore, is not coextensive. Furthermore, a search of the nucleic acid molecules of Group II would require an oligonucleotide search, which is not

likely to result in relevant art with respect to the polypeptide of Group I. As such, it would be burdensome to search the inventions of Groups I and II.

b. The polypeptide of Group I and the antibody of Group III are patentably distinct for the following reasons: While the inventions of both Groups I and III are polypeptides, in this instance, the polypeptide of Group I is a single chain molecule, whereas the polypeptide of Group III encompasses antibodies including IgG which comprises 2 heavy and 2 light chains containing constant and variable regions, including framework regions which act as a scaffold for the 6 complementary determining regions (CDRs) that function to bind an epitope. Thus, the polypeptide of Group I and the antibody of Group III are structurally distinct molecules; any relationship between a polypeptide of Group I and an antibody of Group III is dependent upon the correlation between the scope of the polypeptides that the antibody binds and the scope of the antibodies that would be generated upon immunization with a polypeptide. Furthermore, searching the inventions of Group I and Group III would impose a serious search burden. The inventions have a separate status in the art as shown by their different classifications. A polypeptide and antibody which binds to the polypeptide require different searches. An amino acid search of the full-length protein is necessary for a determination of novelty and nonobviousness of the protein. However, such a search is not required to identify the antibodies of Group III. Furthermore, antibodies which bind to an epitope of a polypeptide of Group I may be known even if a polypeptide of Group I is novel. In addition, the technical literature search for the polypeptide of Group I and the antibody of Group III is not coextensive,

e.g. antibodies may be characterized in the technical literature prior to discovery of, or sequencing of, their binding target.

c. The polynucleotide of Group II and the antibody of Group III are patentably distinct for the following reasons: Polypeptides, such as the antibody of Group III, which are composed of amino acids, and polynucleotides, which are composed of nucleic acids, are structurally distinct molecules. Any relationship between a polynucleotide and polypeptide is dependent upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. In the present claims, a polynucleotide of Group II will not encode an antibody of Group III, and an antibody of Group III cannot be encoded by a polynucleotide of Group II. Therefore, the antibody and polynucleotide are patentably distinct. The antibody and polynucleotide inventions have a separate status in the art as shown by their different classifications. Furthermore, searching the inventions of Groups I and III would impose a serious search burden since a search of the polynucleotide of Group I would not be used to determine the patentability of an antibody of Group III and vice-versa.

d. Invention V, a transgenic animal, Invention VII, a nucleic acid construct, and Invention VIII a pluripotent cell, are structurally and functionally distinct each from the other and from the products of Inventions I, II, and III.

5. The polypeptides of Invention IX, the nucleic acids of Invention X, and the antibodies of Invention XI, the transgenic animal of Invention XIII, the nucleic acid construct of Invention XV, and the pluripotent cell of Invention VIII are independent and distinct, each from each other for

reasons that are analogous and parallel to those set forth above for Inventions I, II, III, V, VII, and VIII.

6. Inventions I-III,VIII and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case each of the products of Inventions I-III and VIII could be used in processes other than the cell identification process of Invention IV. Conversely, pluripotent cells can be identified by means that do not utilize the products of Inventions I-III or VIII or the method of Invention IV.

7. Inventions IX-XI, VIIIand XII are related as product and process of use and are distinct because each of the products of Inventions IX-XI and VIII could be used in processes other than the cell identification process of Invention XII. Conversely, pluripotent cells can be identified by means that do not utilize the products of Inventions IX-XI or VIII or the method of Invention XII.

8. Inventions V and VI are related as product and process of use and are distinct because the invention of Group V, a non-human transgenic animal comprising GCR1 (Fragilis) nucleic acid can be used in processes other than the compound identification process of Group VI. Conversely, a compound that specifically interacts with GCR1 (Fragilis) could be identified without the use of a transgenic animal.

9. Inventions XIII and XIV are related as product and process of use and are distinct because the invention of Group XIII, a non-human transgenic animal comprising GCR2 (Stella)

nucleic acid can be used in processes other than the compound identification process of Group XIV. Conversely, a compound that specifically interacts with GCR2 (Stella) could be identified without the use of a transgenic animal.

10. Inventions IV and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Invention IV is a method of identifying pluripotent cells and Invention VI is a method of identifying a compound capable of interacting specifically with a GCR1 protein. Therefore they are not usable together, they use different products and have different functions.

11. Inventions XII and XIV are unrelated for reasons that are analogous and parallel to those set forth above for Inventions IV and VI.

12. Inventions I-III, VII, VIII are unrelated to Invention VI because none of the products of Inventions I-III, VII, VIII are required or utilized in the method of Invention VI.

13. Inventions IX-XI, XV, VIII are unrelated to Invention XIV because none of the products of Inventions IX-XI, XV, VIII are required or utilized in the method of Invention XIV.

14. Inventions V, VII are unrelated to Invention IV because none of the products of Inventions V, VII are required or utilized in the method of Invention IV.

15. Inventions XIII, XV are unrelated to Invention XII because none of the products of Inventions XIII, XV are required or utilized in the method of Invention XII.

16. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, and have acquired a separate status in the art as shown by their different classifications, and the search required for

any of Group I-XVI is not required for any other of Group I-XVI, restriction for examination purposes as indicated is proper.

17. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

18. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel C Gamett, Ph.D., whose telephone number is 571 272 1853. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571 272 0961. The fax phone number for the organization where this application or proceeding is assigned is 571 273 8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

DCG
Art Unit 1647
27 April 2005

Bridget C. Bunner
patent examiner